

*Surgitron*<sup>®</sup> **F.F.P.F. EMC**<sup>™</sup>



## Quality Record and Maintenance Manual

Cat. No. EMCMM10



*Surgitron*<sup>®</sup> F.F.P.F. EMC<sup>™</sup>  
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# I. DECLARATION OF CONFORMITY

Application of Council Directive: Medical Device Directive (93/42/EEC)

Standards to Which Conformity is Declared:

1. Conforms to the immunity requirements of EN 60601-1-2
2. Conforms to the emissions requirements of EN 60601-1-2 and EN 60601-2-2

For technical support, telephone 516-594-3333 or 800-835-5355,  
Fax 516-569-0054, or email [ellman@ellman.com](mailto:ellman@ellman.com)

Congratulations on your purchase of Ellman International's radiosurgical device, the Surgitron® F.F.P.F. EMC™.

**ellman®** International is the leader in the field of Radiosurgery®. Our innovations, 25+ U.S. Patents, and commitment to our proven record of safety and superior performance is documented in numerous clinical articles and textbooks in the specialties of otolaryngology, ophthalmology, gynecology, dermatology, family practice, plastic surgery, general surgery, podiatry, and neurosurgery.

Be assured that you are testing the safest, most reliable high-frequency radiosurgical instrument available. The following technical and safety information is provided to assist you, the bio-medical engineer, in a thorough, trouble-free performance verification and safety inspection of the Surgitron® F.F.P.F. EMC™.

If you require additional information or have any questions or comments regarding this device, feel free to contact **ellman®** International.

## II. QUALITY RECORD

**ellman International, Inc.**

3333 Royal Avenue, Oceanside, NY 11572 U.S.A  
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### 2.1 GENERAL

a. Model: \_\_\_\_\_

b. Serial Number: \_\_\_\_\_

c. Power Supply Voltage: \_\_\_\_\_

d. Thermo Transformer Type: **MAGNET WOUND**

### 2.2 FIRST DEGREE INSPECTION Inspector: \_\_\_\_\_ Date: \_\_\_\_\_

(Refer to the 500 ohm load output power curve with 20% tolerance.)

Test equipment: Tektronics DPO 4032, Tektronics Probe P5100, 500 ohm Non-Inductive Load, DMM.

#### 1. Operating Modes Inspection (Waveform inspection) and Primary Output Inspection

a. **CUT:** \_\_\_\_\_ (Check waveform with oscilloscope: Pure Filtered Wave)

Dial #	1	2	3	4	5	6	7	8	9	Hi
Power										

b. **CUT COAG:** \_\_\_\_\_ (Check waveform with oscilloscope: Fully Rectified)

Dial #	1	2	3	4	5	6	7	8	9	Hi
Power										

c. **COAG:** \_\_\_\_\_ (Check waveform with oscilloscope: Partially Rectified)

Dial #	1	2	3	4	5	6	7	8	9	Hi
Power										

d. **FULGURATE:** \_\_\_\_\_ (Only an oscilloscope is to be used for this measurement: Spark-Gap)

Dial #	1	2	3	4	5	6
Power						

ROOM TEMP: \_\_\_\_ °F

ROOM HUMIDITY: \_\_\_\_ %

2. Hardware Inspection: (Visual Inspection)

a. Paint Finish                      Pass\_\_\_\_\_                      Fail\_\_\_\_\_

b. Labeling                              Pass\_\_\_\_\_                      Fail\_\_\_\_\_

Inspector: \_\_\_\_\_                      Date: \_\_\_\_\_

**2.3      SECOND DEGREE INSPECTION**

This test is according to UL544 Standard.

Test equipment: HIPOT tester,

1. Dielectric Withstand Inspection:                      Pass\_\_\_\_\_                      Fail\_\_\_\_\_

2. Ground Continuity Inspection:                      Pass\_\_\_\_\_                      Fail\_\_\_\_\_

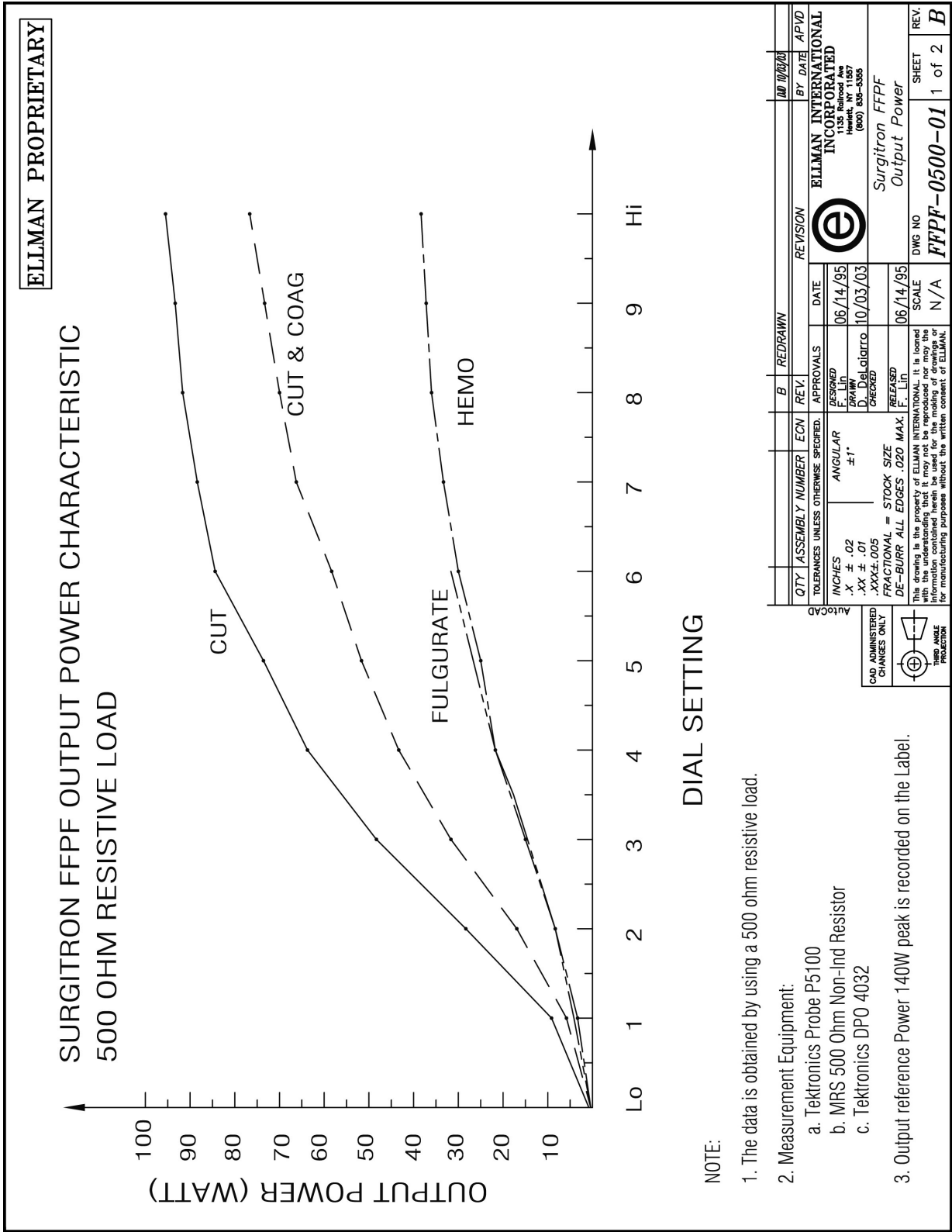
3. Work Bench Practical Test:                      Pass\_\_\_\_\_                      Fail\_\_\_\_\_

20 Mins @ 10 sec.

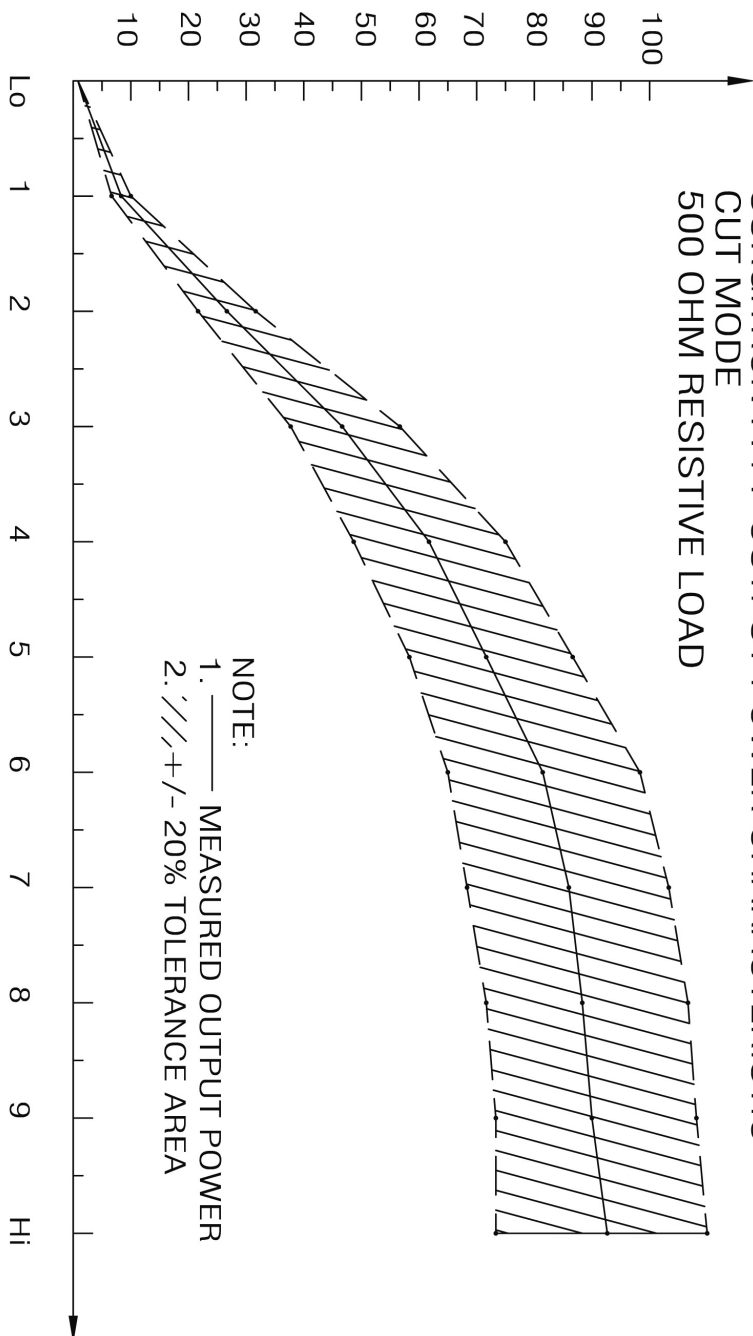
On/ 30 sec. Off

Inspector: \_\_\_\_\_                      Date: \_\_\_\_\_

2.4 OUTPUT POWER CHARACTERISTIC



SURGITRON FFPF OUTPUT POWER CHARACTERISTIC  
CUT MODE  
500 OHM RESISTIVE LOAD



NOTE:  
1. \_\_\_\_\_ MEASURED OUTPUT POWER  
2.  $\pm$  20% TOLERANCE AREA

NOTE:  
1. The data is obtained by using a 500 ohm resistive load.  
2. Measurement Equipment:  
a. Tektronics Probe P5100  
b. MRS 500 Ohm Non-Ind Resistor  
c. Tektronics DP0 4032  
3. Output reference Power 140W peak is recorded on the Label.

DIAL SETTING

AutoCAD		B		REDRAWN		10/10/01	
QTY	ASSEMBLY NUMBER	ECN	REV.	APPROVALS	DATE	REVISION	BY DATE
TOLERANCES UNLESS OTHERWISE SPECIFIED:							
INCHES		ANGULAR					
.X ± .02		±1°					
.XX ± .01							
.XXX ± .005							
FRACTIONAL = STOCK SIZE							
DE-BURR ALL EDGES .020 MAX.							
F.L.N.		ELABOR					
06/14/95							
SCALE		N/A					
DWG NO		FFPF-0500-2					
SHEET		2 of 2					
REV.		B					

ELLMAN INTERNATIONAL  
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Surgitron FFPF  
Output Power

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### III. MAINTENANCE & TROUBLE SHOOTING

The system block diagram and basic circuit schematic are provided here for general review of the basic circuits that make up the Surgitron® FFPF EMC™. They should be reviewed carefully before performing any troubleshooting. Troubleshooting flowcharts are supplied for the more common problems.

The power supply includes the entry module, thermal transformer, fuses and line switch. Four high-power diodes make up the full wave rectifier. The mode selector controls the output waveform rectifier and filter. There are three options from the mode selector:

1. **Fully rectified and filtered**
2. **Fully rectified**
3. **Partially rectified**

They are used to perform pure **Cut**, **Cut and Coag**, and **Hemo**, respectively.

The RF signal network generates a 3.8 MHz high frequency signal as a carrier. This is modulated by the lower frequency signal from the mode selector.

The output power supply controller controls the output impedance matching and, therefore, controls the power output. Power output vs. load impedance test curves are included for your reference, see Fig. 3. This power intensity curve is plotted with a 500 Ohm pure resistance load.

The antenna plate provides the return path for the RF signal. The system output is controlled by operating the footswitch.

The following fault conditions are defined, along with the check procedure and the specific conditions experienced. Step-by-step procedures necessary to isolate the fault are provided so that solutions are achieved.

A. If red AC light does not light up:

1. Check that the power cord is plugged into the wall outlet and the other end is correctly plugged into the receptacle unit.
2. Check fuses; do not use larger than indicated – 1.6 amp/220V or 3.0 amp/117V. Using a larger fuse will damage the Surgitron unit. Replace fuse with P/N: R-EK03A (1.6 amp/220V) or R-EK03B (3.0 amp/117V), as specified in the Surgitron FFPF EMC Repair Kit.
3. If fuse continues to blow, remove four screws from both sides of the unit and carefully remove cover. Check for the following conditions:
  - a. Transformer short circuit – replace P/N R-EK09 (RF Safety Thermo Transformer).
  - b. Check short circuit on diode PCB or replace P/N R-EK13.
  - c. Check short circuit on R1 or replace P/N R-EK15.
  - d. Check short circuit on R5 or replace P/N R-EK16.
4. Check AC indicator bulb; if it is open-circuited, replace P/N R-EK05A (AC Light Diode). Check the voltage output of the power entry module. If there is no voltage, replace the power entry module, R-EK17.
5. Check secondary output voltage from transformer:
  - a. Between green wires should be >6.3V.
  - b. Between red wires should be >600V.
  - c. If these conditions are not met, replace P/N R-EK09 (RF Safety Thermo Transformer).
6. Visually inspect the unit for shorted or burnt resistors and capacitors. Inspect wire connections and solder joints.
7. Tube may be defective; replace P/N R-EK10 (RF Amplifier Power Tube).

B. If RF indicator does not light when foot-switch is pressed:

1. Allow a 15 second warm-up period before activating the unit.
2. Defective foot-switch; replace with P/N R-EK2 (EMC RF Foot Control).
3. Turn on the unit and allow a 15 second warm-up period. Visually inspect tube filament. If it does not glow (and AC indicator light is on), replace with P/N R-EK10 (RF Amplifier Power Tube).
4. Check RF light bulb. If it is open-circuited, replace with P/N R-EK14.
5. Check ground system to see if green/yellow ground wire is connected. This wire must be attached to chassis ground.
6. Check shorted or burnt components on R-EK16. If there is problem, replace R-EK16.

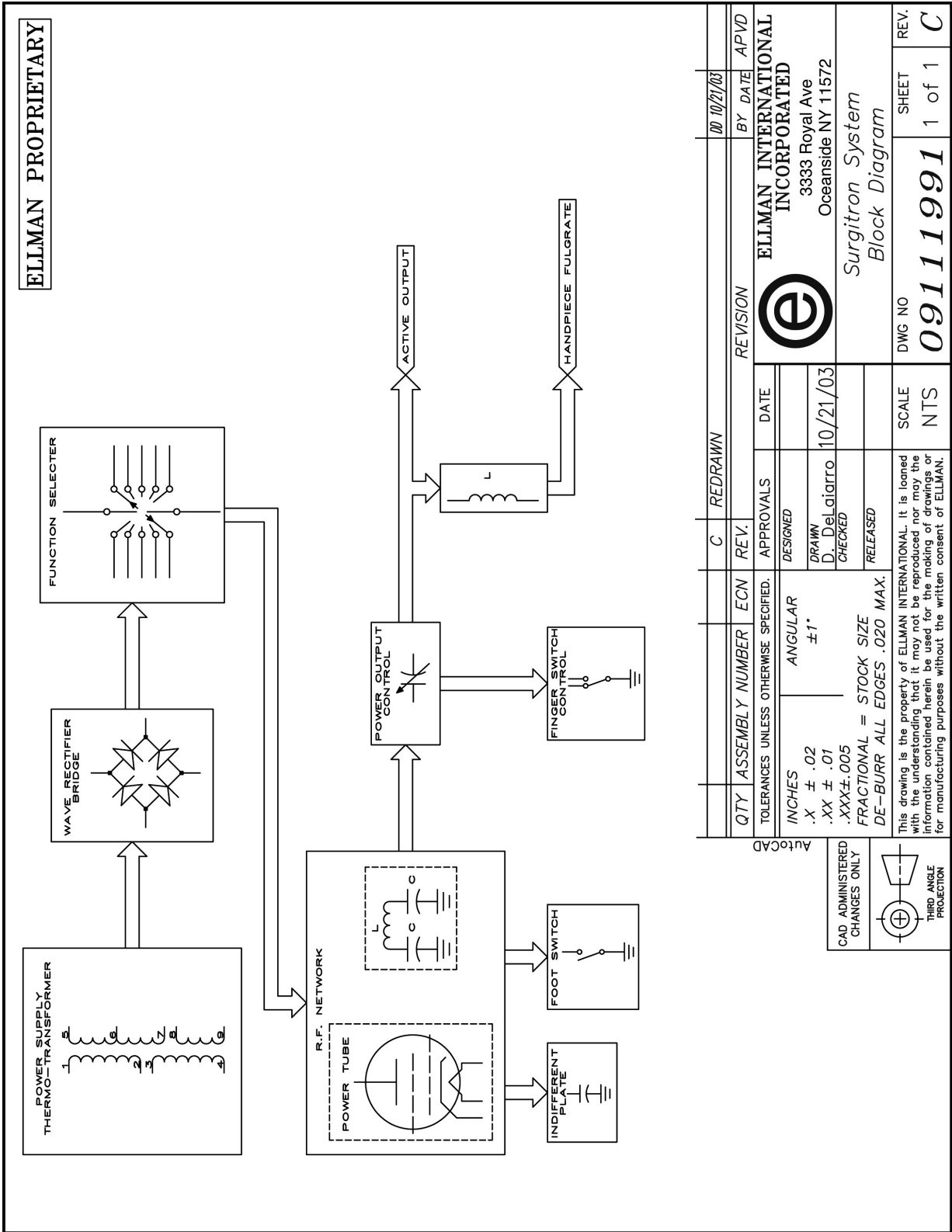
#### Transformer Wiring

220 VAC - the Black and the White transformer primary wires should be used.

110/120 VAC - the Black and the Black/Red transformer primary wires should be used.

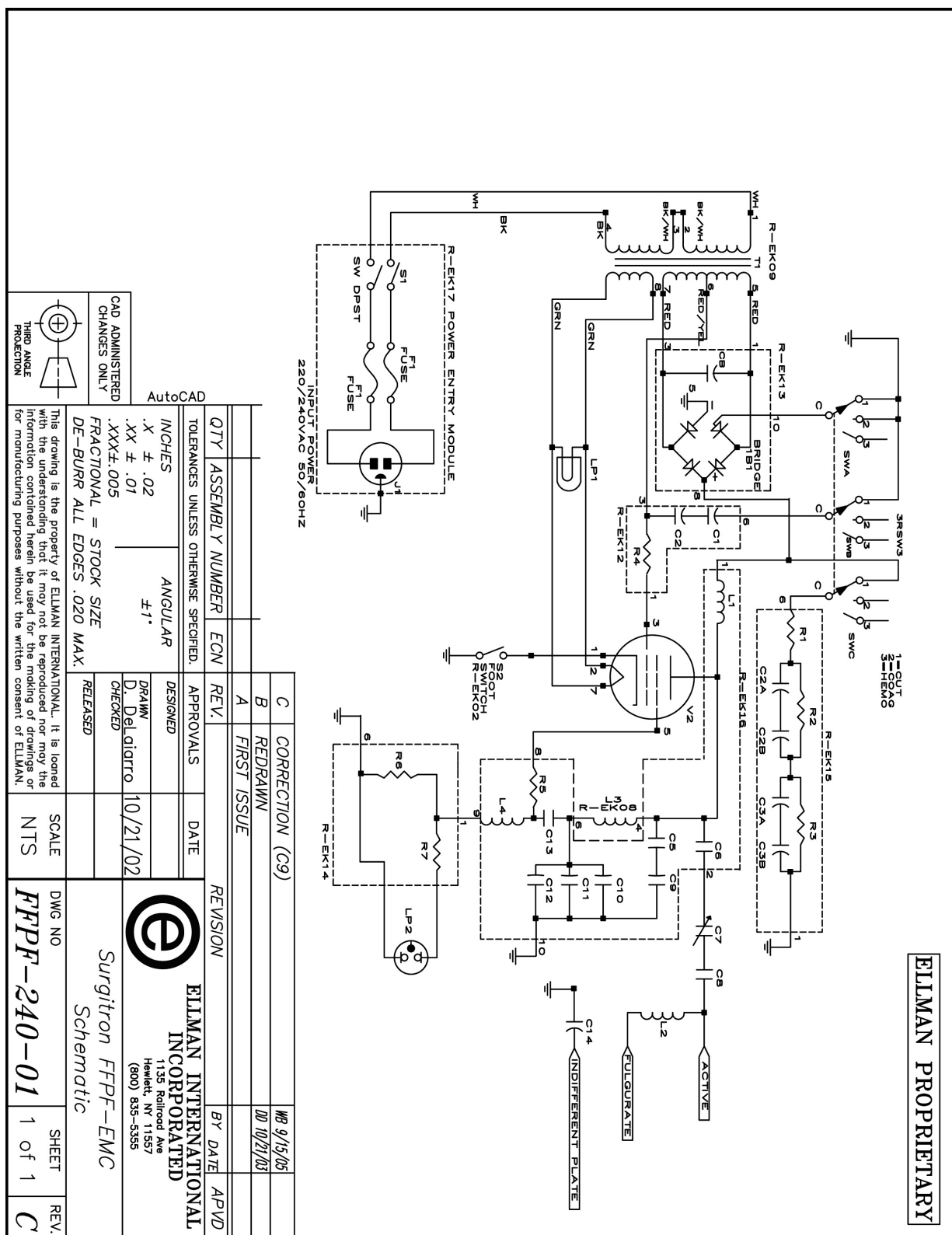
100 VAC - the Black and the Black/white transformer primary wires should be used.

3.1 SURGITRON SYSTEM BLOCK DIAGRAM



### 3.2

## BASIC CIRCUIT DIAGRAM



### 3.3 SURGITRON F.F.P.F. EMC REPAIR KIT

Item	Description
R-EK01A	Black RF Function Selector Knob
R-EK01B	Black RF Power Control Knob
R-EK02	EMC RF Foot Control
R-EK03	3.0 Amp EMC RF Safety Fuse, 117v
R-EK03B	1.6 Amp EMC RF Safety Fuse, 220v
R-EK04A	Green Female Connector
R-EK04B	Black Female Connector
R-EK04C	White Female Connector
R-EK05A	AC Light Diode
R-EK05B	RF Light Diode
R-EK06A	Green AC Light Cap
R-EK06B	White AC Light Cap
R-EK07	RF Insulated Power Control
R-EK08	RF Inductor Coil 17uH
R-EK09	RF Safety Thermo Transformer, 700v
R-EK09/7A	RF Safety Thermo Transformer, 700v w/Audio
R-EK10	RF Amplifier Power Tube
R-EK11	PC Board, EMC-A, Main Board
R-EK12	PC Board, EMC-B, 2-Gang + R4 Board
R-EK13	PC Board, EMC-C, Rectifier Board
R-EK14	PC Board, EMC-D, R6 & R7 Resistor Board
R-EK15	PC Board, EMC-E, 4-Gang
R-EK16	PC Board, EMC-F
R-EK17	AC Power Entry Module
R-EK18A	EMC RF Enclosure - Base
R-EK18B	EMC RF Enclosure - Cover
R-EK19A	EMC Handle, Black
R-EK20	Silicone Rubber Feet (pkg of 4)
R-EK21	RF Waveform Rotary Switch
R-EK22	Hospital-grade RF Power Cord
R-EK23	Audio Board

## NOTES

[illegible]





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